UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, STATE OF NEW JERSEY, STATE OF NEW YORK, and STATE OF CONNECTICUT, ***ex rel.* MICHAEL WALDMAN,** **Plaintiff/Relator,** **vs.** **SPECTRA HOLDCO, LLC f/k/a SHIEL HOLDINGS LLC and SPECTRA LABORATORIES, INC.,** **Defendants.**	**Civil Action No. 17-CV-2732** **Hon. Nicholas G. Garaufis, S.U.S.D.J.** **Hon. Steven M. Gold, U.S.M.J.** **THIRD AMENDED QUI TAM COMPLAINT** **JURY TRIAL DEMANDED**

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THIRD AMENDED COMPLAINT FOR RETALIATION UNDER THE FALSE CLAIMS ACT

On behalf of the United States of America, the State of New Jersey, and the State of New York, Plaintiff and Relator Michael Waldman ("Relator"), by and through Relator's attorney, files this third amended *qui tam* action[1] against Defendants Spectra Holdco, LLC, formerly known as Shiel Holdings LLC, ("Shiel"), and Spectra Laboratories, Inc. ("Spectra"), (collectively "Defendants") and alleges as follows:

I. INTRODUCTION

1. Relator Michael Waldman previously filed this *qui tam* lawsuit (originally in the District of New Jersey, later transferred to this Court) on behalf of the United States, New Jersey, New York and Connecticut Governments, alleging that Defendants submitted false and fraudulent claims for reimbursement of medical-laboratory services to Medicare, Medicaid, and other government health-insurance programs, by creating, altering, or otherwise keeping false and fraudulent healthcare documentation (including having sales reps and other employees add "covered" diagnostic codes to billing records which were never chosen and/or approved by the ordering doctor), and by inducing and rewarding patient referrals by providing doctors free goods and services which constituted illegal kickbacks, all in violation of the False Claims Act, 31 U.S.C. §§ 3729 *et seq.* (the "FCA") and State analogues.

2. Relator also sought to recover damages for unlawful employment retaliation and termination pursuant to 31 U.S.C. § 3730(h).

3. After the Federal and State Governments elected not to intervene in this action, the operative Complaint was unsealed, as well as an operative complaint in *United States et al.*

[1] This Third Amended Complaint is filed pursuant to the Court's Order of April 19, 2023. *See* Minute Entry dated April 19, 2023. Relator originally filed this action under seal as a John Doe but is now identifying himself in this amended pleading.

ex rel. YNKDY-2 v. Shiel Medical Laboratory et al., No. 1:16-cv-1090-NGG-TAM (E.D.N.Y), a previously-filed *qui tam* which substantively asserted the same claims against the same parties.

4. Relator files this Third Amended Complaint omitting his previously-asserted *qui tam* claims and proceeding solely on his retaliation claims under 31 U.S.C. § 3730(h). Contemporaneous with this filing, Relator has filed a Notice of Voluntary Dismissal of the *qui tam* claims, with prejudice as to himself and without prejudice as to the Governments.

II. SUMMARY OF ALLEGATIONS

5. Relator, who was employed by Defendants for several years, brought this whistleblower action to expose the illegal billing and marketing schemes engaged in by the management of Defendant Shiel, a diagnostic medical laboratory business based in Rockleigh, New Jersey, which primarily served the greater New York metropolitan area.

6. Medicare and Medicaid statutes and regulations require documentation of medical necessity for diagnostic medical tests, including requiring the ordering doctor to provide a diagnosis code indicating the patient's actual or suspected disease or condition. However, these government programs do not reimburse for all tests regardless of diagnosis code. Some tests are considered "non-covered" for certain diagnosis codes, and any claim for reimbursement of such tests will be rejected.

7. Generally in those circumstances, either the patient must pay the lab or the lab must "eat" the cost of the test.

8. However, for at least from 2011 through 2017, Shiel management willfully and intentionally disregarded these statutes and regulations, in order to maximize company revenues and personally profit.

9. Rather than follow the compliant procedures outlined above, Shiel's billing department generated a "Missing Diagnosis Code" report (internally referred to as a "code sheet" or "code") when a claim for reimbursement is rejected.

10. The sales representative ("sales rep") responsible for the account was given the code sheet and instructed to send the sheet back to the doctor's office and ask the doctor to pick a different, covered diagnostic code, and sign the sheet. (Sales reps either did this personally or sent a service rep or other employee). The sheet was transmitted or delivered back to Shiel's billing department, which re-submitted the claim for reimbursement.

11. Even Shiel's supposedly "correct" procedure was problematic, however, because by Medicare regulations and best practices, as acknowledged in Shiel's own billing guidance for providers, the doctor was supposed to choose the diagnosis code that most accurately reflected the patient's actual condition, not any code that will get the claim paid.

12. However, Shiel's fraudulent scheme went much further. Because some providers' lab orders resulted in huge volumes of code sheets, the responsible sales reps and employees found it virtually impossible to get the doctors to review charts, choose new codes, and sign off on all of them (even assuming that an ethical doctor would agree to change the code at all). Nonetheless, management put tremendous pressure on sales reps and other employees to get the coding sheets filled out with covered diagnosis codes and with documented doctor approval (or in the Shiel vernacular, "get the codes done." This pressure included verbal chastising and criticism as well as threats of demotion, pay cuts or even termination.

13. Shiel also provided incentive compensation for its sales reps, whereby sales reps and certain employees tasked with servicing customer relationships got a percentage of collected revenues from lab tests ordered by their customers. This provided a strong economic incentive

for the sales reps and other employees to "get the codes done" in any way possible, because re-submitted reimbursement claims generated revenue for the company and thus money in their pockets.

14. With management knowledge and approval, many (indeed most) sales reps committed outright fraud in order to "get the codes done." Among other things, they filled out the code sheets themselves (usually without consulting the patient chart, which would be a HIPAA violation in any event) and faked doctors' signatures or approvals, sometimes by taking sheets to doctors' offices and getting staff to stamp the sheets and "borrowing" the office fax machine to fax them back to Shiel's billing department, so it appeared that the sheets were actually approved by the doctor and transmitted by the doctors' office staff. Sales reps and employees often induced or rewarded the staffs' compliance by providing free meals and other gratuities.

15. Shiel management knew which employees were particularly efficient at preparing this fraudulent documentation, and assigned those employees to handle especially voluminous code sheets or uncooperative doctors' offices.

16. Similarly with management knowledge and approval, Shiel sales personnel also engaged in a kickback scheme, whereby Shiel provided doctors with items and services of value in order to induce or reward their referrals. Among other things, sales executives and sales reps gave doctors expensive and highly-sought-after sports tickets, high-value luxury gift cards, and expensive meals and entertainment. These employees faked receipts to get reimbursement for these expenses.

17. Shiel also paid kickbacks to referring doctors in the form of free services, particularly by assigning phlebotomists who were on the Shiel payroll full-time to doctors'

offices, where they performed general office services well beyond the permissible collection of specimens.

18. Defendants' fraud generated tens of thousands of fraudulent and false claims submitted to Government healthcare programs, which cost the Federal and State Governments well over one hundred million taxpayer dollars.

19. Relator adamantly refused to participate in Defendants' fraudulent schemes, and repeatedly brought them to the attention of management, expressly warning them of potential legal liability because they were submitting false and fraudulent billing documentation to the Government. Management, however, not only knew about these schemes, but was actively promoting and perpetrating them. Accordingly, Defendants ignored Relator's concerns, and furthermore unlawfully discriminated against him in retaliation for his whistleblowing, causing him among other things to lose significant compensation.

20. Ultimately, in further unlawful retaliation, Defendants terminated Relator and then prevented him from being re-employed by the company that acquired Shiel.

III. JURISDICTION, VENUE, AND SPECIAL REQUIREMENTS

21. Pursuant to 28 U.S.C. § 1331, this Court has jurisdiction over the subject matter of this civil action because it arises under the laws of the United States, in particular, the False Claims Act, 31 U.S.C. § 3729, *et seq*.

22. In addition, the FCA specifically confers jurisdiction upon United States District Courts under 31 U.S.C. § 3732. This Court has personal jurisdiction over Defendants pursuant to 31 U.S.C. § 3732(a) because Defendants maintained offices and conducted business in the Eastern District of New York.

23. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) because Defendant Shiel maintained its primary offices and laboratory in Brooklyn, New York, and otherwise did and does business in this District, and because certain acts complained of herein occurred in this District.

24. This Court has personal jurisdiction over Defendants pursuant to 31 U.S.C. § 3732(a) because the False Claims Act authorizes nationwide service of process and Defendants have sufficient minimum contacts with the United States of America.

25. In accordance with 31 U.S.C. § 3730(b)(2), the original Complaint was filed *in camera*, remained under seal per this Court's Orders, and was not served on the Defendants until the Court so ordered.

IV. THE PARTIES

26. Plaintiff/Relator Michael Waldman was employed by Defendants as a Senior Sales Representative from November 2012 until December 31, 2017.

27. Shiel Medical Laboratory, Inc. was a for-profit New York Corporation with its principal offices and primary laboratory facility located at 8 King Road, Rockleigh, New Jersey, 07647.

28. Shiel Holdings, LLC was a for-profit Delaware Limited-Liability Corporation. Its principal place of business was 8 King Road, Rockleigh, New Jersey, 07647. In or about December 2017, Shiel Holdings, LLC became Defendant Spectra Holdco, LLC, which is a Delaware limited liability company.

29. From in or about November 2013 until in or about December 2017, Shiel was a wholly-owned subsidiary of Spectra Laboratories, Inc. From in or about December 2017, Spectra Holdco, LLC has been a wholly-owned subsidiary of Spectra Laboratories, Inc.

30. Defendant Spectra Laboratories, Inc. is a for-profit Nevada Corporation, with a principal place of business located at 920 Winter Street, Waltham, Massachusetts, 02451. Since in or about 1997, Spectra has been a wholly-owned subsidiary of Fresenius Medical Care Holdings, Inc.

V. GOVERNING LAWS, REGULATIONS, AND CODES OF CONDUCT

A. The Federal False Claims Act

31. Originally enacted in 1863, the FCA was substantially amended in 1986 by the False Claims Amendments Act. The 1986 amendments enhanced the Government's ability to recover losses sustained as a result of fraud against the United States. Further clarifying amendments were adopted in May 2009 and March 2010.

32. The FCA imposes liability upon any person who "knowingly presents, or causes to be presented [to the Government] a false or fraudulent claim for payment or approval"; or "knowingly makes, uses or causes to be made or used, a false record or statement material to a false or fraudulent claim"; or "knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government." 31 U.S.C. § 3729(a)(1)(A), (B), (G). Any person found to have violated these provisions or conspired to have violated these provisions is liable for a civil penalty of up to $11,000 for each such false or fraudulent claim, plus three times the amount of the damages sustained by the Government.

33. Significantly, the FCA imposes liability where the conduct is merely "in reckless disregard of the truth or falsity of the information" and further clarifies that "no proof of specific intent to defraud" is required. 31 U.S.C. § 3729(b)(1).

34. The FCA also broadly defines a "claim" as one that includes "any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that – (i) is presented to an officer, employee, or agent of the United States; or (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government – (i) provides or has provided any portion of the money or property requested or demanded; or (ii) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded." 31 U.S.C. § 3729(b)(2)(A).

35. The FCA empowers private persons having information regarding a false or fraudulent claim against the Government to bring an action on behalf of the Government and to share in any recovery. The complaint must be filed under seal without service on any Defendant. The complaint remains under seal while the Government conducts an investigation of the allegations in the complaint and determines whether to intervene in the action. 31 U.S.C. § 3730(b).

36. The FCA also provides a cause of action for retaliation to any person "discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment because of lawful acts done by the employee, contractor, agent or associated others in furtherance of an action under this section or other efforts to stop 1 or more violations of [the FCA]." 31 U.S.C. § 3730(h).

37. A Relator prevailing on a retaliation claim is entitled to "2 times the amount of back pay, interest on the back pay, and compensation for any special damages sustained as a result of the discrimination, including litigation costs and reasonable attorneys' fees." *Id*.

B. Federal Government-Funded Health Assistance Programs

1. Medicare

38. Medicare is a federal government-funded medical assistance program, primarily benefiting the elderly, that was created in 1965 when Congress enacted Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395 *et seq.* Medicare is administered by the federal Centers for Medicare and Medicaid Services ("CMS"), which is a division of the U.S. Department of Health and Human Services ("HHS").

2. Medicaid

39. The Medicaid program was created in 1965 when Congress enacted Title XIX of the Social Security Act to expand the nation's medical assistance program to cover the medically needy aged, the blind, the disabled, and needy families with dependent children. 42 U.S.C. §§ 1396-1396v. The Medicaid program is funded by both federal and state monies, (collectively referred to as "Medicaid Funds"), with the federal contribution computed separately for each state. 42 U.S.C. §§ 1396b; 1396d(b). At the federal level, Medicaid is administered by CMS. Medicaid is used by 49 states, each of which has a state Medicaid agency to administer the program.

40. Each state is permitted, within certain parameters, to design its own medical assistance plan, subject to approval by the HHS. Among other forms of medical assistance, the states are permitted to provide medical assistance from the Medicaid Funds to eligible persons for diagnostic procedures. 42 U.S.C. § 1396a(10)(A); 1396d(a)(12).

3. General Provisions Applicable to Both Medicare and Medicaid

a. Prohibitions Against Claims for Reimbursement for Services that were Not Provided as Claimed, were Not Medically Necessary, or are Otherwise False or Fraudulent

41. Federal law prohibits a person from knowingly presenting or causing to be presented to Medicare or Medicaid a claim for a medical or other item or service that the person knows or should know was "not provided as claimed," a claim for such items or services that the person knows or should know is "false or fraudulent," or a claim that is "for a pattern of medical or other items or services that [the] person knows or should know are not medically necessary." 42 U.S.C. §§ 1320a-7a(a)(1)(A), (B) & (E).

42. Federal law similarly penalizes a person who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim for payment for items and services furnished under a Federal health care program." *Id*. § 1320a-7a(a)(8).

43. Violation of this section is subject to a civil monetary penalty of $11,000[2] for each item or service, plus damages measured as three times the amount of each claim submitted, and exclusion from further participation in the programs. *Id*. § 1320a-7a(a).

VI. SPECIFIC ALLEGATIONS

A. *Medicare Billing for Diagnostic Laboratory Procedures*

44. As a provider of diagnostic laboratory procedures or tests that bills Medicare, Medicaid, and other government health programs, Shiel was required to comply fully with all applicable laws and regulations.

45. Except under very limited and well-defined circumstances, the law forbade Shiel sales reps from giving gifts, or things or services of value, to referring doctors and other health care providers. Doctors are supposed to choose diagnostic labs based on merit alone, considering such things as quality of work and turnaround time for test results.

[2] By regulation, the maximum per-claim penalty increases annually.

46. When ordering a diagnostic test for a Medicare-covered patient, the doctor is supposed to indicate his or her diagnosis (or suspected diagnosis) by providing on the order form (or electronically) the corresponding diagnosis code (or codes) from the International Classification of Diseases and Related Health Problems ("ICD"), the current version of which is ICD-10.

47. As Shiel stated in its Medicare billing guidance for providers, CMS "has implemented uniform National Coverage and Administrative Policies for clinical laboratory services to ensure the medical necessity of certain services rendered to Medicare beneficiaries." Therefore, the Medicare carrier (*i.e.*, the fiscal intermediary) "requires medical necessity documentation to determine coverage." (www.shiel.com/for_physicians/billing_information) ("Shiel Website") (last visited Nov. 22, 2016); *accord* 42 C.F.R. § 410.32(d)(2).

48. At least on its website, Shiel correctly instructed providers how appropriately to provide documentation of medical necessity by selecting a diagnosis code:

> Whenever you order a test that is subject to NCD or LCD, an ICD-[10] code is required on the test request form. The ICD-[10] code should indicate the medical necessity that you, in your judgment, believe is appropriate for the test. Please provide the ICD-[10] code(s) which most accurately describe the patient's condition. ***Do not choose a code merely to secure claim payment.*** . . . The ICD-[10] code that you provide must appear in the patient's medical record in order to support the medical necessity of the testing in the event of a post-payment review.

Shiel Website, *supra* (emphasis added).

49. These legal requirements exist because, apart from certain specific exceptions, Medicare generally does not reimburse "screening" tests, *i.e.*, a diagnostic test that is given without the doctor suspecting that the patient has a particular disease or condition.

50. Medicare best practices also call for the doctor to also have each patient who is prescribed a diagnostic test read and sign an Advance Beneficiary Notice ("ABN"). This is a

document whereby the patient acknowledges that Medicare may find the test medically unnecessary and refuse to reimburse, and the patient agrees in those circumstances to pay "out of pocket."

51. As Shiel acknowledged in its billing guidance for providers, absent a signed ABN, a lab may not bill the patient for the non-covered tests:

> In the event that a test is determined by Shiel Medical Laboratory's Medicare carrier to be medically unnecessary, the laboratory may only bill the patient if an Advance Beneficiary Notice (ABN) has been completed and signed by the patient before the specimen is collected.

Shiel Website, *supra*.

52. Thus, in the normal course of business at a compliant lab, if the prescribing doctor chose a non-covered diagnosis code, and the patient had not signed an ABN, the lab would not get paid for the diagnostic test, and it had to "eat" the cost (*i.e.*, suffer a loss of revenue).

B. ***Shiel's Fraudulent Coding and Billing Practices***

53. From at least in or about 2007 through the date that this Complaint was originally filed, Shiel regularly submitted false and fraudulent claims for reimbursement of diagnostic laboratory procedures, primarily blood tests and pathology.

54. Specifically, when a physician ordering a diagnostic test provided a diagnosis code (ICD-9 or ICD-10) that Medicare, Medicaid, or another health-insurance program did not accept to justify reimbursing the test that was ordered, Shiel's claim for reimbursement would be rejected.

55. When that happened, the billing department generated a "Missing Diagnosis Code" report for each rejected claim, indicating both the "submitted diagnosis" (*i.e.*, the diagnosis code that the physician specified) and the type of test that had been performed.

56. The billing department also generated these reports when doctors failed to provide any diagnosis code when ordering a test.

57. In the right column of the report was a blank box labeled "DX" (medical shorthand for "diagnosis." At the bottom of the report was a signature line labeled "Doctor's Signature."

58. The billing department sent these reports, which were internally known as "code sheets" or simply "codes," to the sales reps who handled the respective doctors.

59. Ostensibly, the reps were supposed to take the reports back to the doctor's office and ask the doctor to determine whether another (covered) diagnosis code would be appropriate given the patient's condition, or, where the doctor had provided no diagnosis codes, to provide a covered code. If so, the doctor was supposed to indicate that code in the "DX" box and sign the report.

60. Shiel could then submit or re-submit the claim for reimbursement, and presumably it would get paid.

61. However, as a matter of course, Shiel did not follow these simple steps. Instead, Shiel resorted to shortcuts that constituted fraud, and, in the case of claims submitted to Government healthcare programs, violations of the False Claims Act.

62. Shiel management pressured the sales reps to "get the codes done" – in other words, to get the reports filled out and approved by any means necessary.

63. This translated to sales reps and other employees impermissibly filling out the covered diagnosis codes themselves, and using deceptive and fraudulent means to get the reports "signed" by the doctors.

64. Among other things, sales reps and other employees took the filled-out reports to doctors' offices and cajoled staff members to allow them to use the doctors' signature stamps to "approve" them. Sales reps also would have the doctors' staff fax the "completed" reports back to Shiel, or ask the staff to "borrow" the fax machine, ostensibly for a personal matter, and fax

them to Shiel themselves. Thus, when the reports were received at Shiel they falsely appeared to have been prepared and approved by a doctor and sent by the doctor's office staff.

65. Sometimes sales reps bribed or rewarded compliant staff members with gifts such as free meals.

66. In the most extreme instances, sales reps and other employees would "cut and paste" a copy of the doctor's signature onto the report, or simply forge it.

67. Shiel management well knew that the sales reps and other employees were engaged in this illegal conduct. For example, those few sales reps who refused to engage in misconduct to "get the sheets done" suffered large revenue decreases from their accounts, which management saw on periodic financial reports.

68. Shiel managers also knew that certain employees "specialized" in "getting the codes done" in the fraudulent and illegal fashion described herein.

69. For example, Shiel referring doctor David Klug routinely omitted diagnosis codes from his test orders. Regional Sales Manager Steve Morea assigned Client Service Rep Olga Jedinak to "get the codes done" since a large volume of tests ordered by Dr. Klug had not been reimbursed.

70. However, when Olga attempted to meet with Dr. Klug to go over the reports (which numbered approximately 200), he phoned Morea and angrily complained that he had no time to go over so many reports.

71. Morea knew that Olga would not engage in the fraud necessary to "get the codes done." Accordingly, Morea assigned the task to account executive named Erica Ryan.

72. Ryan was considered the "go-to" person within Shiel to complete huge volumes of "codes" in a short time, because she had practically memorized the covered diagnostic codes and

could quickly review the reports and input covered codes. More importantly, management knew that she was willing and able to commit fraud to get the job done.

73. Upon information and belief, Ryan engaged in many of the fraudulent acts described herein, as there was no other way she could get such huge volumes of reports "done" within the deadlines set by management.

74. Defendants permitted Senior Vice President of Sales Sal Prifitera to run Shiel's sales as a personal fiefdom. Among other things, he routinely made employment decisions about his reports (including hiring and firing) without the involvement of Shiel HR.

75. For example, Prifitera had two service reps, Robin Cochrane and Doreen Mirlas, as direct reports. Under Shiel's usual corporate structure, service reps would be four management levels below Prifitera. However, upon information and belief, Prifitera assumed direct supervision over Cochrane and Mirlas to enable him to direct them in "getting codes done" and other illicit activities.

76. District Manager James Gordon was one of Shiel's longest-serving sales reps. His predominant customer base was nursing homes, and he sold to and serviced up to 100 nursing homes in the New York metropolitan area at a time.

77. In part because diagnostic tests in nursing homes are frequently ordered by nursing staff (supervised by a doctor) rather than directly by a patient's treating physician, the nursing homes generated huge volumes of code sheets, which management required Gordon to complete and submit.

78. Gordon complained about the immense financial and psychological pressure that his supervisors have applied, including constant phone calls and threats of demotion and pay cuts, to compel him to "get the codes done." However, as time went on, he grew increasingly concerned

about the propriety of Shiel's practices concerning the code sheets, and resisted filling out and otherwise fabricating diagnosis codes.

79. The sheer volume of the "code sheets" – in some cases, hundreds (or even thousands) of pages' worth of "missing" codes – coupled with managers' constant demands that the reps get the reports "done" within extremely short timeframes (*e.g.*, by the end of the week, ASAP, within a day), made it physically impossible for sales reps to get proper authorization for each completed report.

80. In other words, when a manager ordered a sales rep to get a large stack of "codes" "done" in a short time, that manager knew (or at a minimum, should have known) that it would be impossible for the sales rep (or his client service reps) to take each report to a doctor, ask the doctor for a different code (and moreover a "covered" one that would enable insurance reimbursement), get the doctor to sign, and deliver the report back to billing.

81. Even more tellingly, when employees *did* comply with those orders, Shiel managers knew (or at a minimum, should have known) that it *was* impossible for such a large volume of reports to have been completed (and similarly improbably, with most if not all of the "new" diagnostic codes ones being "covered" ones) and doctor-approved by the given deadline.

82. Notwithstanding their website guidance for providers, Shiel also never required doctors to obtain signed ABNs from patients, even though there were huge numbers of tests that Medicare was not reimbursing.

83. The fact that Shiel did not require signed ABNs further demonstrated the existence of the fraudulent coding scheme, because without a signed ABN, Shiel had no way to get paid for a non-covered diagnostic test. Because management relied on the sales reps and other employees to unlawfully "get the codes done," Shiel did not need to bill patients for non-covered tests.

84. Upon information and belief, based possibly on Relator's whistleblowing (as described more fully herein), in or about October 2016, Shiel management ordered the billing department to stop printing and distributing the code sheets.

85. Nonetheless, on or about November 16, 2016, Sal Prifitera hosted a meeting of the entire sales force. At that meeting, large stacks of code sheets, apparently recently printed, were present. The sales reps were eager to obtain these stacks, because they knew it would mean money in their pockets if they were completed and submitted. However, Prifitera refused to hand them out, because he explained (in substance and in part) that it would not be compliant, and they needed to get the code sheets out of the reps' hands.

86. It soon became apparent to Relator that these code sheets were printed at the direction of managers who were directly involved in committing the fraudulent scheme.

Sales Reps' Incentive Compensation Propelled the Coding Fraud

87. Shiel management used the sales reps' incentive compensation structure as both a carrot and a stick in Defendants' fraudulent billing scheme.

88. Shiel sales reps were compensated in part on a commission basis. Usually, sales reps would be rewarded with up to ten percent of revenues collected as a commission or bonus. The client service reps, who handled routine matters for existing customers, were paid 0.5 to 2 percent of revenues. If sales reps failed to meet their quotas and targets, management would reprimand them and/or write them up with threats of termination.

89. Because the "missing diagnosis code" reports documented diagnostic tests which Shiel had performed, but for which it had not been reimbursed by insurance, those "codes" not only represented potential revenue for Shiel, but also cash for the sales and service reps' pockets.

90. To pressure sales reps to "get the codes done," managers constantly reminded them how much money the uncompleted reports represented to the reps in lost commission.

91. As one manager texted a sales rep: "Please get ur [*sic*] codes in this week. U [*sic*] have $6k outstanding. $ that could b [*sic*] in ur [*sic*] pocket That's a big % of ur [*sic*] total cash"

92. Another manager texted a photo of an inches-high stack of reports to a sales rep, along with the following message: "These are my codes. Never had this many before. Please keep a log or make copies on what you [h]and in. Educate your clients. There are thousands and thousands of dollars there"

93. A regional sales manager texted a photo of his hand next to a thick stack of reports to colleagues, complaining that it was "over four fingers high!!!" Erica Ryan texted back, "And I have the other ½ [*sic*] of them!"

Kickbacks

94. Upon information and belief, Shiel regularly, and illegally, provided referring physicians and their medical practices free goods and services.

95. Among other things, Shiel gave doctors valuable electronic equipment such as desktop and laptop computers, iPads, software, and wireless service. These computers and devices were not dedicated for specific medical use related to the diagnostic-testing services Shiel provided to patients, therefore they did not fall within any regulatory safe harbor.

96. For example, Sal Prifitera provided one medical practice with all-new Apple computers and MacPractice medical-office software, all of which was worth in excess of ten thousand dollars. Again, this equipment was not limited in use to medical diagnostics, but was intended to be used (and was used) as the doctor's office computer equipment. (Notably, Prifitera

also ran Shiel's client IT operation, creating a serious conflict of interest with his sales responsibilities).

97. Shiel also provided phlebotomists free of charge to several referring doctors' offices, whose ostensible sole purpose was to collect blood samples which would be tested by Shiel. However, those phlebotomists regularly engaged in other, unrelated office duties, such as answering phones, taking patients' blood pressure, filing, and filling in for regular staff during breaks or absences. The provision of those additional duties fell outside the regulatory "safe harbor" established by HHS/OIG for phlebotomists.

98. Some phlebotomists were also trained and directed to fill in and submit coding sheets as part of the previously-described illegal scheme.

99. Many Shiel sales reps paid for gift cards and expensive dinners for their clients and prospects, for which they claim reimbursement by disguising these expenditures as legitimate expenses such as catered lunches for office staff in-service meetings.

100. For example, sales rep Steve Morea personally purchased gift cards (usually in $100 denominations) which he distributed at holiday time to his customers. He submitted this expense for company reimbursement by creating or generating false receipts for non-round numbers.

101. Until in or about 2015, Shiel regularly provided referring doctors with valuable tickets to New York area sporting events, including Giants football, Mets baseball, and Nets basketball. As with the dinners, these purchases were usually disguised by the company, which had sales reps purchase the tickets individually and then reimbursed them as other, permitted expenses.

102. Although Shiel has "officially" restricted reps from providing items of value to their customers, management not only ignores that continued practice, it actively (but quietly) condones it. For example, as of the 2015 holiday season, Shiel prohibited sales reps from sending gift baskets to customers. However, for the 2016 holiday season, sales managers including Cathy Winburn verbally instructed sales reps to purchase holiday catered lunches and other items for their customers, and to submit their claims for reimbursement as legitimate expenses such as making a presentation on insurance risk to doctors' office staffs over lunch.

VIII. DEFENDANTS UNLAWFULLY RETALIATED AGAINST RELATOR, TERMINATED RELATOR'S EMPLOYMENT, AND PREVENTED HIS RE-EMPLOYMENT

A. Relator Blows the Whistle on Defendants' Fraud

103. As described previously, over time Shiel put increasing pressure on sales reps, including Relator, to fraudulently add codes to patient records and claim documentation to increase corporate revenue. Relator consistently refused to engage in this fraud.

104. In or about early 2016, Relator began complaining to management about the "get the codes done" practice. During a one-on-one meeting, Jim Murphy, Shiel's Vice President of Clinical Sales (though in reality entirely beholden to Prifitera) raised concerns (for the first time) about Relator's sales performance. Relator pointed out that his refusal to engage in the coding fraud was having a direct impact on his customer revenues as well as his incentive compensation, but complained that he should not be penalized for refusing to participate in misconduct. In any event, Relator noted that if he was given proper credit for his customers he would meet Shiel's stated performance expectations.

105. On or about August 15, 2016, Murphy again met with Relator to discuss his sales performance. Relator complained that Shiel had not provided him (or the sales reps more

generally) clarify concerning their sales goals and resulting compensation. Relator raised additional concerns that Shiel's lab was unable to handle volumes of new business, and that its billing and collections system was dated, inefficient, and likewise incapable of handling additional volume. Murphy agreed with these points.

106. Relator again complained about his continuing discomfort with Shiel's fraudulent coding practices. Murphy and Relator agreed that a followup meeting that would include Shiel human-resources and compliance officials should be scheduled.

107. No such meeting took place. However, in an email dated August 29, 2016, Murphy falsely mischaracterized their August 15 conversation. Murphy claimed that he had expressly criticized Relator's sales performance. Murphy further claimed that he had informed Relator that his entire employment with Shiel he had failed to grow his customer base, and further that he had not met the goals of Shiel's new sales compensation program (which, as stated, provided significant financial incentives for the reps to engage in the coding fraud). Murphy then informed Relator that a formal written warning had been placed in his personnel file (again, falsely claiming that he had informed Relator of this on August 15). In any event, the formal warning was a first for Relator.

108. Subsequent to the August 29 email, Relator and Murphy exchanged additional emails in which among other things Murphy disclaimed management promises made earlier in 2016 that Relator would get quota credit for certain customers including nursing homes.

109. On or about September 6, 2016, Relator sent an email to Peter Connelly, who was Compliance Officer for Fresenius Spectra Labs East and thus for Shiel after it was acquired.

110. Relator reported that Shiel documentation was frequently missing ICD10 diagnosis codes in, and that sales and service reps were being directed to fill out missing code sheets with

the most "flexible" codes (i.e., codes which would render the diagnostic testing reimbursable). Relator stated that he refused to comply, and that he had directed his service reps not to fill in missing codes either.

111. Relator stated that because his lab billings were missing codes, they were not getting reimbursed, so management had written him up for not making his numbers. Nonetheless, Relator reasserted that he would not comply just to make quota.

112. Relator pointed out that submitting documentation to the federal government with made-up codes that the prescriber did not supply would be illegal and could put the company at risk. Relator noted that he had brought this issue to the attention of Shiel Vice President Jim Murphy but that Murphy ignored him. He ended the email by asking Connelly to investigate.

113. On or about September 9, 2016, Connelly responded, thanking Relator for raising concerns and assuring him that the company was "taking it very seriously." He referred the matter to Sarah Schuler, a Fresenius in-house attorney. On or about September 21, 2016, Schuler emailed Relator to say that the company had asked her to look into his concerns, had retained outside counsel (Hogan Lovells) to assist her, and asked Relator to schedule an interview. The interview took place on or about September 29, 2016. Schuler and outside counsel again assured Relator that they considered his concerns to be serious and that they would investigate.

B. **Defendants Retaliate Against Relator for his Whistleblowing**

114. Shortly after initially raising these concerns, Relator began to experience a negative and increasingly hostile work environment. Among other things, management began excluding Relator from potentially (or previously) lucrative clients and territories, including in New York City, yet they (particularly Prifitera) enabled their favored reps to service multiple territories and otherwise increase their potential earnings.

115. Management (including Murphy and Prifitera) later reneged on written promises and representations they had made concerning the allocation of quotas (and resulting incentive compensation) among sales reps, including specific promises and representations made to Relator.

116. For example, the Jewish Home of Rockleigh was a nursing home that neighbored Shiel's Rockleigh headquarters but had never been a customer. In or about early 2016, Relator and sales representative James Gordon solicited the Jewish Home and won its business. Shiel's lab proved incapable of handling the additional volume, resulting in test result delays and inaccurate results as well as billing problems. However, Relator and Gordon personally stepped in to address the problems, and as a result the Jewish Home not only remained a Shiel customer but continued to increase its referral volumes.

117. Relator inquired as to receiving credit for the new business. On or about May 19, 2016, Catherine Winburn, Director of Sales and Relator's supervisor (who reported to Jim Murphy, who in turn reported to Prifitera), related that Murphy had confirmed that Relator and Gordon would get 50/50 credit for the business as they had worked together to obtain and secure the customer. Accordingly, Relator estimated that his compensation for this customer would exceed $25,000.00 per year.

118. In or about mid-December 2016, Sal Prifitera falsely accused Relator and Gordon of failing to provide appropriate levels of service to the Jewish Home, and that the nursing home would be switching labs. Prifitera falsely claimed that he was responsible for getting Shiel this customer, but also told both Relator and Gordon not to waste their time going back to them as he said the nursing home's management was only using Shiel "for pricing," meaning that they were using Shiel's prices to leverage better terms with another lab. Prifitera used these lies to deny Relator his promised credit and compensation.

119. When Relator received Prifitera's emails, he contacted the Director of Nursing at the nursing home, who assured him there was no problem and that he actually intended to continue increasing the amount of business he was sending to Shiel.

120. Relator and Gordon confronted Prifitera with the facts they had learned, and challenged his lie that he was responsible for getting Shiel the nursing home as a customer.

121. Prifitera's lies about the nursing home demonstrated that he, on behalf of Defendants, was retaliating against Relator by trying falsely to paint Relator as inattentive and nonresponsive to important Shiel customers, so as to get Relator removed from customer accounts and thus lose valuable compensation (and potentially his job).

122. Defendants also retaliated and discriminated against Relator by applying corporate rules concerning sales territory and customer assignments to Relator that management did not apply to other sales reps.

123. For example, Manhattan Labs, based in New York City, was a major Shiel competitor. Dr. Yaffe was a New York gastroenterologist who referred a large volume of business to Manhattan Labs. Relator had established a relationship with Dr. Yaffe and was close to closing a deal where Dr. Yaffe would switch to Shiel for his referrals. Prifitera told Relator to hold off because he was working on a direct relationship between Manhattan Labs and Shiel (which would have produced even larger volumes) but promised Relator that he would get credit for the new business.

124. However, after the deal between Shiel and Manhattan Labs was consummated, Prifitera invoked the sales territory and customer assignment rules in denying Relator credit for the new business. When Relator complained, Prifitera told him that he never had a chance of

closing a deal either with Dr. Yaffe or Manhattan Labs. This discriminatory act of retaliation alone cost Relator approximately $100,000.00 in annual compensation.

125. On or about November 9, 2016, Relator again complained to Murphy about his inconsistent and often contradictory statements to Relator about what his quota was and whether he had met it, including statements about whether diagnostic tests ordered for nursing home patients would count for his quota. Among other things, he noted that many of his fellow sales reps were upset about the same issues he had raised, including billing and the lab's quality and quantity capabilities. Relator also complained that he had been reassigned to sales territories that had fewer prospects and produced less revenue than the geography assigned to other sales reps.

126. Murphy did not reply, but instead forwarded the email to Prifitera. Prifitera replied defensively, denying that anyone made promises, assigned sales territories, or moved goalposts that affected Relator's compensation, and essentially blaming Relator for his own difficulties. Among other things, Prifitera claimed that because Relator had been assigned sales territories within New York City, he could not complain about any inability to generate business. He also excoriated Relator for citing complaints from his colleagues, blamed Relator for fostering discontent among Shiel employees, and demanded that Relator describe to management in detail his internal discussions. Prifitera also falsely claimed that Relator had violated his Shiel confidentiality agreement by communicating with a employees of a competing lab, obliquely threatening legal action.

127. Prifitera also included in the email response a "Written Warning" instructing Relator to cc him on any further communication referencing comments that management allegedly made.

128. On or about November 14, 2016, Relator sent another email to Priftera responding to his false accusations, including calculations of revenue he had generated from new customers including the nursing home. Relator demonstrated that if management used the correct calculations and gave him the quota credit they had promised him earlier in the year, his performance metrics would be in line with Shiel's stated goals. He also pointed out that while he did have sales territory within New York City, other sales reps were assigned geographic areas within the City that were larger and/or much more lucrative.

C. The Government Investigates Shiel and Retaliation Against Relator Increases

129. By in or about November 2016, Hogan Lovells had broadened its internal investigation to review allegations of billing fraud, kickbacks, and other malfeasance. On multiple occasions, Relator complained to outside counsel, as well as to Schuler, who also was personally involved in the investigation, about his concerns that he was being retaliated against.

130. On or about December 5, 2016, Fresenius management circulated an email to all Shiel management and employees informing them that the company had received a subpoena from the Justice Department and instructing them, among other things, to preserve documents.

131. Shortly thereafter, Relator was informed by sales representative Neil Wyman that Murphy had been speculating to various sales reps that the subpoena was the result of Relator's complaining. Relator promptly emailed Schuler to report this and ask her to have management refrain from such defamatory speculation.

132. Relator then learned that Prifitera and Murphy, in communications with other employees, were accusing Relator of being the whistleblower who had triggered the Federal investigation.

133. Relator reported this incident to Schuler. He also reported to Schuler the harassment and discriminatory treatment by management (including Murphy and Prifitera's preferential treatment of certain reps, and hiring and promotion without HR involvement), as well as the fact that Sheryl Morgan (the HR head) had ignored these complaints and failed to take any actions in response, even though Prifitera was flouting HR's authority and corporate rules.

134. In or about early January 2017, Relator received a self-evaluation form for his upcoming annual performance review. He was shocked to see that one of the major/primary objectives on which he was to be evaluated was "collects missing ICD10 codes and provides accurate and timely reports as requested by management." Relator complained to management, among other things informing Schuler (copying outside counsel) that he believed that "collecting" missing codes was improper, that in the wake of the investigation he thought the company had stopped that practice, and that he was extremely uncomfortable and concerned that his evaluation would include that metric. He informed her that he would inform his manager that he would continue to refuse to "collect codes" and that he objected to being evaluated on that metric. She responded with an acknowledgment that reps were no longer responsible for obtaining missing codes, and that he should write "not applicable" on that section when filling out the self-evaluation.

135. On or about March 29, 2017, Relator had his annual performance review, attended by his direct supervisor Cathy Winburn and her boss Jim Murphy, VP Clinical Sales. Relator was surprised that Murphy attended because usually his review meeting was with only his immediate supervisor, and because Murphy worked in California.

136. For the first time in his employment with Shiel, Relator received all negative scores, most of them 4s (1 being "outstanding" and 5 being "poor"). In previous reviews, he consistently received 3s (meeting expectations) or better.

137. One of the 4s was for the "collecting codes" metric; another 4 was for "honesty and integrity." Relator again voiced his objections and asked why he was being evaluated for collecting codes when officially that practice was supposed to have stopped. Murphy acknowledged that Peter Connolly, Fresenius's Compliance Officer, had flagged it as a compliance issue, but explained that because the company had still been holding reps responsible for missing codes in 2016, he was being evaluated on that metric. Justifiably outraged, Relator refused to sign or otherwise acknowledge the review.

138. On his way out of the meeting, Relator ran into Connolly. He recounted what had just happened and told him that despite previous assurances that he would not be retaliated against, he felt abused and harassed. Connolly commented that he was surprised that the codes were still part of the evaluation.

139. Relator wrote up a response to the metrics (many of which had arbitrarily been changed from Shiel's longstanding performance evaluation criteria) and provided it to Prifitera, Murphy, and Winburn. Among other things, Relator asked why he had received a poor rating for "honesty and integrity." He noted that he was "the only one who was truthful and honest" and expressly accused management of retaliating.

140. On or about March 15, 2017, Lloyd Castillo, Director of Laboratory Operations for Spectra/Shiel, was terminated, allegedly in retaliation for reporting numerous unlawful practices to management, including to Peter Connolly. Castillo subsequently filed a lawsuit alleging retaliation under New Jersey law. *Castillo v. Spectra East, Inc. et al.*, Civ. A. No. 2:17-cv-7156 (SDW)(CLW)(D.N.J.). It appears that the lawsuit was settled in 2019.

141. Well into 2017, even after the Government began investigating, Defendants were still directing sales reps to get doctors to fill in missing ICD10 codes on billing sheets.

Management directed the reps to send the code sheets to doctors' offices with boilerplate cover letters requesting that they be completed. In a March 29 email, Jim Murphy advised sales managers that he and Sal Prifitera had warned Fresenius management that sending such sheets to doctors' offices, particularly "in mass" [*sic*] would cause a negative response from the doctors "and may cost us business," but admitted that "Corporate has demanded they all be sent."

D. **Fresenius sells Shiel to Quest, and Defendants Further Retaliate Against Relator**

142. On or about September 26, 2017, Fresenius announced publicly that it was selling its diagnostic laboratory business.

143. On or about September 27, 2017, Quest entered into an agreement with Fresenius to acquire Shiel.

144. The same day, all Shiel employees were summoned to a meeting in Rockleigh. Management informed the sales reps that they would be meeting with them individually. When Relator was called in, management informed him that he would be terminated effective December 31, 2017. He was instructed to stay home for the duration, not to call on or communicate with any customers, and that he would be paid through the end of the year. A senior Quest manager present at the meeting informed Relator, that although he was being terminated from Shiel, he would have the opportunity to apply for employment with Quest.

145. After the meeting, Relator immediately left the building and drove home. However, Prifitera falsely reported to Sheryl Morgan in HR that Relator had confronted him after the meeting and physically threatened him. Morgan conveyed this to Relator, who explained that it never happened. Relator suggested to Morgan that she obtain security camera video to confirm that he had immediately left the building.

146. Over the following days, Relator spoke to several of his fellow sales reps and learned that Quest had hired nearly everyone to continue their positions after December 31, 2017. Relator thus learned that he had been singled out not to be offered employment by Quest. Tellingly, Quest had hired Sal Prifitera as a senior sales executive.

147. On or about October 2, 2017, Relator emailed Murphy to ask about the status of his commissions and whether he would be paid what he had earned. Initially, Murphy told him that commission reports would not be distributed to reps who had been terminated. However, when Relator followed up with Morgan, she told Relator that he had not been terminated but was continuing as an employee until the end of the year (albeit without any work duties) and was thus entitled to commissions. Relator later received the commissions to which he was entitled.

148. Even after Relator's official termination, Sal Prifitera continued to harass and retaliate against him.

149. On or about December 15, 2017, Relator received a telephone call from a police officer with the Northvale, NJ police department. The officer said that one of Relator's co-workers had reported a workplace argument with Relator, and that Relator had verbally threatened him. The officer also said that the co-worker had reported that Relator had been posting threatening (though anonymous) messages about the co-worker on CafePharma, an online message board frequented by pharmaceutical sales employees. Relator responded that none of these allegations was true, and no action was taken. Relator believes that Sal Prifitera (who lives in Northvale) falsely reported these accusations to the police department.

IX. CLAIMS FOR RELIEF

FIRST CAUSE OF ACTION

(False Claims Act: Retaliation)
(31 U.S.C. § 3730(h))

150. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 149 of this Complaint as if fully set forth herein.

151. As specifically set forth in the foregoing Paragraphs, particularly Paragraphs 101 through 149, Defendants discharged, demoted, threatened, harassed, and/or discriminated against the Relator in the terms and conditions of his employment, because Relator lawfully reported to his superiors, what he believed to be fraudulent conduct or wrongdoing, in violation of 31 U.S.C. § 3730(h).

152. As a direct result of Defendants' violations, Relator has suffered injury, among other things in the form of lost compensation and benefits, and non-economic damages for emotional distress and other pain and suffering. Relator seeks compensatory damages and other appropriate statutory relief pursuant to this Section.

X. DEMANDS FOR RELIEF

WHEREFORE, Relator demands judgment against the Defendants, ordering that:

a. Relator be awarded such relief as is appropriate under the provisions of 31 U.S.C. § 3730(h) for retaliatory discharge, including:

(1) two times the amount of back pay plus interest;

(2) compensation for special damages sustained by Relator in an amount to be determined at trial;

(3) litigation costs and reasonable attorneys' fees; and

(4) such punitive damages as may be awarded under applicable law;

d. Relator be awarded all costs and expenses of this action, including attorneys' fees as provided by 31 U.S.C. § 3730(o) and any other applicable provision of the law; and

e. Relator be awarded such other and further relief as the Court may deem to be just and proper.

TRIAL BY JURY

Relator hereby demands a trial by jury as to all issues.

SPIRO HARRISON & NELSON

By: _____

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Dated: May 22, 2023